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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,992	04/17/2001	Yuichi Obata	L0461/7112 (JRV/MXA)	6680

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EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/11/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/835,992

Applicant(s)

OBATA, YUICHI

Examiner

David J Blanchard

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/14/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 13-15, 31 and 32 are pending.

Claims 1-12 and 16-30 have been canceled in the amendment filed as Paper No. 12 on 7/14/2003.

2. Claims 13-15, 31 and 32 are under examination to the extent that the claims are drawn to methods for detecting antibodies that bind sterol carrier protein-x/sterol carrier protein-2.

3. The following office action contains new ground of rejections.

Specification

4. The disclosure is objected to because of the following informalities:

It is requested that applicant update the priority information on page 1, lines 6 and 8 of the disclosure with the patent number for U.S. Serial. No. 08/896,164. The patent number is 6,218,521 B1. Likewise, it is requested that applicant update U.S. Serial Nos. 08/580,980 and 08/479,328 on page 3, line 1 of the disclosure with their patent numbers 6,025,191 and 5,698,396, respectively.

Appropriate correction is required.

Claim Objections

5. Claim 31 is objected to because of the following informalities:

Art Unit: 1642

a. Claim 31 is drawn in part to a nonelected invention. Applicant's elected Group III in Paper No. 7 (8/8/2002) drawn to a method of detecting gastric cancer by assaying for antibodies and further elected antibodies that bind to sterol carrier protein-X/sterol carrier protein-2 (Group I) in Paper No. 9 (11/19/2002). Applicants did not elect methods drawn to determining the level of (i) a peptide derived from a sterol carrier protein-X/sterol carrier protein-2 or methods of determining the level of (ii) a cytolytic T cell specific for cells presenting a peptide derived from sterol carrier protein-X/sterol carrier protein-2.

b. Claim 31 recites "to determine level" which does not appear to be proper. Consider revising with "to determine the level".

c. Claim 31 recites "following progress" which does not appear to be proper. Consider revising with "following the progress".

Appropriate correction is required.

Rejections Withdrawn

6. The rejection of claims 13-15, 31 and 32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

7. The rejection of claims 13-15, 31 and 32 under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the

Art Unit: 1642

application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

Response to Arguments

8. The rejection of claims 13-15, 31 and 32 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

The response filed 7/14/2003 has been carefully considered, but is deemed not to be persuasive. The response states that the declaration of Yuichi Obata filed 7/14/2003 submits that 8/44 gastric cancer patient samples had antibodies that bind sterol carrier protein X and none of the 55 control individual samples tested contained antibodies that bind sterol carrier protein X. In contrast, the declaration states that 6/44 gastric cancer patients had antibodies that bind sterol carrier protein X and none of the 50 control individual samples tested contained antibodies that bind sterol carrier protein X. Applicants conclude that the data demonstrate that using the method outlined in the specification detects antibodies to sterol carrier protein X in gastric cancer patients. In response to these arguments, while the declaration teaches the detection of antibodies that bind sterol carrier protein-X in gastric cancer patients, the declaration does not demonstrate that the presence of antibodies that bind the sterol carrier protein X/sterol carrier protein-2 polypeptides encoded by SEQ ID Nos. 19, 20, 21 and 22 are specific to gastric cancer patients and the specification provides insufficient evidence or nexus

Art Unit: 1642

between the presence of antibodies that specifically bind sterol carrier protein X/sterol carrier protein-2 and polypeptides encoded by SEQ ID Nos. 19, 20, 21 and 22 and gastric cancer. Applicant's have not demonstrated that the sterol carrier protein X/sterol carrier protein-2 polypeptides encoded by SEQ ID Nos. 19, 20, 21 and 22 are found in gastric cancer patients or whether there are detectable antibodies bound to the polypeptides encoded by SEQ ID Nos. 19, 20, 21 and 22 in gastric cancer patients or whether these antibodies would be present in other cancers. Further, the declaration admits that only 14% (6/44) of gastric cancer patients that already have gastric cancer are effectively diagnosed using the claimed methods as having gastric cancer. The specification does not teach an assay that specifically detects the antibody bound to the polypeptides encoded by SEQ ID Nos. 19, 20, 21 and 22 or antigenic fragments thereof that are diagnostic of gastric cancer. Additionally, applicants have not taught any antigenic fragment of the sterol carrier protein X/sterol carrier protein-2 polypeptides encoded by SEQ ID Nos. 19, 20, 21 and 22 that are diagnostic of gastric cancer and a fragment may be a single amino acid.

No specific direction or guidance is provided to assist one skilled in the art in the method for determining gastric cancer in a patient by detecting antibodies bound to sterol carrier protein-x/sterol carrier protein-2 because the specification does not disclose how the bound antibodies are to be detected such as by isotype or some other structural feature of the bound antibodies required to practice the claimed method.

Art Unit: 1642

The issue here is whether applicant's specification, which provides no working examples, enables any person skilled in the art to use the full scope of the claimed diagnostic methods.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 31 and 32 are indefinite for reciting "parameter" in claim 31. Is the "parameter" an antibody that binds sterol carrier protein-X/sterol carrier protein-2 or is some other parameter contemplated by the method?

b. Claims 31 and 32 are indefinite for reciting "said peptide of said protein" in claim 31. There is insufficient antecedent basis for this limitation in the claim because the claims are being examined to the extent that the claims are drawn to methods of detecting antibodies that bind sterol carrier protein-X/sterol carrier protein-2.

c. Claims 31 and 32 are indefinite for reciting "following progress of a therapeutic regime" in claim 31. It is unclear how the progress of a therapeutic regime designed to alleviate gastric cancer is to be followed. Does the phrase "following progress of a

Art Unit: 1642

therapeutic regime" mean that the level of an antibody (i.e. parameter) that binds sterol carrier protein-X/sterol carrier protein-2 will increase or decrease over the time-course of a therapeutic regime designed to alleviate gastric cancer? Additionally, is an increase in antibody detection diagnostic of gastric cancer progression or regression?

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 13-15, 31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are directed towards a method of determining gastric cancer in a patient by assaying a sample obtained from a patient for an antibody that binds a sterol carrier protein-X/sterol carrier protein-2 encoded by a nucleic acid comprising a nucleotide sequence selected from the group consisting of SEQ ID Nos. 19, 20, 21, and 22.

The specification does not describe sterol carrier protein-X/sterol carrier protein-2 proteins that are encoded by SEQ ID Nos. 19, 20, 21 and 22. The specification

Art Unit: 1642

discloses sterol carrier protein-X/sterol carrier protein-2 polynucleotides, which vary substantially in length and also in nucleotide composition (see attached sequence alignment of SEQ ID Nos. 19, 20, 21 and 22). The specification does not identify or describe the 5' and 3' regulatory regions and untranslated regions essential to the function of the claimed invention, which are required since the claimed invention currently encompasses the sterol carrier protein-X/sterol carrier protein-2 gene. The art indicates that multiple transcription start sites have been identified for the human sterol carrier protein-X/sterol carrier protein-2 gene (Ohba et al. Genomics 24: 370-374, 1994) (see abstract) and the human sterol carrier protein-X/sterol carrier protein-2 gene gives rise to two mRNAs: a 2.8 kb mRNA encoding sterol carrier protein-X, a peroxisome-associated thiolase, and a 1.5 kb mRNA encoding sterol carrier protein-2, which is thought to be an intracellular lipid transfer protein (Ohba et al. Biochemistry 34: 10660-10668, 1995) (see abstract). The specification has not identified any sterol carrier protein-X/sterol carrier protein-2 protein encoded by SEQ ID Nos. 19, 20, 21, and 22 or any open reading frame or function or whether any of SEQ ID Nos. 19, 20, 21, and 22 encode sterol carrier protein-X or sterol carrier protein-2.

The instant disclosure of a species of polynucleotides encoding sterol carrier protein-X/sterol carrier protein-2 polypeptides does not adequately describe the claimed sterol carrier protein-X/sterol carrier protein-2 polypeptides encoded by SEQ ID Nos. 19, 20, 21 and 22 that are diagnostic of gastric cancer. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or

Art Unit: 1642

correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant sterol carrier protein-X/sterol carrier protein-2 polypeptide is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The skilled artisan cannot envision the detailed structure of the encompassed sterol carrier protein-X/sterol carrier protein-2 polypeptides and therefore, conception is not achieved until reduction to practice has occurred. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

Conclusions


13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number through January 19, 2004 is (703) 605-1200. The examiner can be reached at (571) 272-0827 after January 21, 2004. The examiner can normally be reached at (703) 605-1200 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, can be reached at (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Art Unit: 1642

Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,
David J. Blanchard
703-605-1200



LARRY R. HELMS, PH.D
PRIMARY EXAMINER